Remarks

Claims 13-27 are currently pending in this application.

Applicants have amended claim 19 to indicate that the process comprises adding to the composition a mucous membrane compatibility enhancing amount of a surfactant mixture. The term "mucous membrane compatibility enhancing amount" replaces the term "effective amount" and clarifies the intention of the claim. Applicants respectfully submit that no new matter has been entered in the application by way of amendment to claim 19. The amendment to claim 19 is fully supported in the specification and claims as originally filed.

Before discussing the rejection over the prior art, Applicants deem it prudent to set forth what they consider to be their invention. As presently claimed, the invention is directed to a composition comprising:

(a) an oligoglycoside selected from the group consisting of alkyl oligoglycosides, alkenyl oligoglycosides and mixtures thereof;

(b) a foam stabilizer selected from the group consisting of partial esters of tartaric acid with C_{6-22} fatty alcohols, salts of partial esters of tartaric acid with C_{6-22} fatty alcohols, partial esters of malic acid with C_{6-22} fatty alcohols, salts of partial esters of malic acid with C_{6-22} fatty alcohols, partial esters of citric acid with C_{6-22} fatty alcohols, salts of partial esters of citric acid with C_{6-22} fatty alcohols, and mixtures thereof; and

(c) optionally, at least one active ingredient selected from the group consisting of cosmetic-active ingredients, pharmaceutical-active ingredients, and mixtures thereof with the proviso that (a) and (b) are employed in a ratio by weight of from about 60:40 to 40:60.

As presently claimed in the composition of claim 13, the critical portions of the composition are a mixture of an oligoglycoside or alkenyl oligoglycoside with a foam stabilizer comprising the partial esters of tartaric acid, malic acid and citric acid with C_{6-22} fatty alcohols and salts thereof.

The composition has dermatological and ophthalmic mucous membrane compatibility and excellent foam stability. Applicants respectfully submit that the present invention is not obvious over the prior art references cited by the Examiner.

Claims 13-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kahre et al. (U.S. 6,432,419) in combination with Burns (DCI, March 1997). Applicants respectfully submit that Kahre et al. and Burns, whether considered alone or in combination, neither teach nor suggest the present invention.

Kahre et al. discloses and claims a composition containing a cosmetic or pharmaceutical composition containing an auxiliary or an additive and

I) a non-ionic surfactant selected from the group consisting of alkyl or alkenyl oligoglycosides and fatty acid-N-alkylpolyhydroxyalkylamides; and

II) a fatty compound wherein said fatty compound consists of an oil selected from the group consisting of

(a) polyolpolyhydroxy stearate; and

(b) hydroxy carboxylic acid esters wherein the fatty compound and the nonionic surfactants are present in a ratio by weight of 10:90 to 90:10, and wherein the total quantity of auxiliaries and additives in a composition is from 1-50% by weight based on the weight of the composition.

It is the Examiner's contention that the term "hydroxycarboxylic acid esters" refers to both full esters and partial esters of hydroxy polycarboxylic acids. Applicants respectfully submit that the Examiner's interpretation of the term "esters" is untenable in view of the teachings of the reference.

Firstly, the specification discloses four preferred hydroxycarboxylic acids for forming the esters. Three of the four preferred hydroxycarboxylic acids can form only full esters with a fatty alcohol since the compounds contain only one carboxyl group. Only one ester of a hydroxycarboxylic acid with a fatty alcohol is exemplified in the reference. The hydroxy fatty acid ester with a fatty alcohol (oleyol lactate) is a full ester since lactic acid contains

only a single carboxyl group. Likewise the two additional preferred hydroxycarboxylic acids ricinoleic acid and hydroxystearic acid, contain only one carboxyl group and therefore cannot form a partial ester with a fatty alcohol.

Kahre et al. teach that esters of lactic acid, malic acid, tartaric acid, and citric acid can be reacted with fatty alcohols to form esters useful in the practice of the invention. There is no mention of partial esters at any point in Kahre et al. and no exemplification of any esters of hydroxypolycarboxylic acids.

The rejection based on Kahre et al. is based on speculation and hindsight reconstruction of Applicant's invention by the Examiner. Applicants submit that speculation and hindsight reconstruction of Applicant's invention are not a basis for a rejection under 35 U.S.C. 103(a).

Applicants submit that on the face of the Kahre et al. reference in which three of the four hydroxycarboxylic acids form only full esters and only one ester is exemplified which is a full ester, Applicants submit that the Examiner's speculation has no basis in fact and must have been prompted by a reading of the present application. Applicants therefore respectfully submit that Kahre et al. neither teaches nor suggests a composition containing a partial ester of malic acid, tartaric acid, or citric acid with a C_{6-22} fatty alcohol or salt thereof.

Applicants respectfully submit that Kahre et al. is deficient in neither teaching nor suggesting a combination of an alkyl or alkenyl polyglycoside and a partial ester of malic acid, citric acid, or tartaric acid with a C_{6-22} fatty alcohol and salts thereof.

The deficiencies in Kahre et al. are not cured by combination with Burns. Burns discloses sodium cocopolyglucose tartrate, disodium coco polyglucose sulfosuccinate, and disodium cocopolyglucose citrate. It is the Examiner's position that sodium cocopolyglucose tartrate and disodium cocopolyglucose citrate are fatty acid partial esters of citric acid and tartaric acid. Applicants respectfully submit that the Examiner's understanding of the compounds is untenable. Applicants respectfully submit that an alkyl

or alkenylpolyglucose is not considered a fatty alcohol in the art. In fact, the structure does not conform to the Examiner's own definition of a fatty alcohol which appears at page 5, lines 2-3, of the Official Action. At page 5, lines 2-3, the Examiner states:

> "A fatty alcohol in a long-chain alcohol, i.e. a carbon chain typically having more than 6 carbons and at least one OH group."

Applicants respectfully submit that the alkyl or alkenyl polyglucoside is not a fatty alcohol according to the definition provided by the Examiner.

Applicants herewith submit page 570 from Hawley's Condensed Chemical Dictionary, 12th ed., 1987, Richard J. Lewis, editor. A glycoside (glucoside) is defined as:

> "One of a group of organic compounds, of abundant occurrence in plants which can be resolved by hydrolysis into sugars and other organic substances known as aglycones. Specifically glycosides are acetals which are derived from a combination of various hydroxy compounds with various sugars. They are designated individually as glucosides, mannosides, galactosides, etc. Glycosides were formerly called glucosides, but the latter term now refers to any glycoside having glucose as its sugar constituent."

In view of the definition of a glycoside, and the Examiner's definition of a fatty alcohol, Applicants respectfully submit that an alkyl or alkenyl polyglucoside does not conform to the definition of a fatty alcohol. As set forth in Hawley's Condensed Chemical Dictionary, an alkyl or alkenyl polyglucoside is an acetal and not a fatty alcohol.

In view of the Examiner's definition of a fatty alcohol and the dictionary definition of a polyglucoside, Applicants respectfully submit that Burns is not pertinent and does not cure the deficiencies in Kahre et al.

Applicants submit that a polyglucoside as defined in Hawley's Condensed Chemical Dictionary, 12th edition, is not a fatty alcohol but an acetal which contains groups which can contain carbon chains separated by oxygen atoms to provide the series of carbon

chains in the acetal structure. The Examiner appears to be basing the rejection on the premise that any organic compound with an OH group is a fatty alcohol.

At page 7, first full paragraph of the Official Action, the Examiner states: "It is respectfully pointed out that the instant claims 14 and 21 are product-by-process claims". Applicants respectfully request that the Examiner reexamine claims 14 and 21. Claim 14 is directed to a composition and not a product-by-process.

Claim 21 is directed to a process dependent on claim 19. Applicants respectfully request that the Examiner reconsider the nature of claims 14 and 21.

At page 7 the Examiner rejects claims 19-27 over the combination of Kahre et al. and Burns. Applicants respectfully submit that the above discussion clearly shows that Kahre et al. and Burns are not pertinent to the present invention.

Applicants respectfully submit that nowhere in Kahre et al. is the use of a partial ester of a hydroxy fatty acid disclosed or suggested. As discussed above, Burns does not teach or suggest a partial ester of a hydroxy fatty acid with a fatty alcohol. Applicants therefore respectfully submit that the combination of references neither teaches nor suggest the present invention.

Claims 13-15, 17-21, 23-24 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-10 of U.S. 6,432,419 (Kahre et al.). Applicants respectfully submit as discussed above Kahre et al. neither teaches nor suggests the present invention. Kahre et al. discloses compositions which do not read on the claims in the present application. Applicants therefore respectfully request that the Examiner reconsider the rejection on the grounds of obviousness-type double patenting.

At page 10, first full paragraph of the Official Action, the Examiner states:

> "As the term "ester" encompasses both partial and full ester forms, and because fabrication of an ester oil would inherently yield a mixture of

> partial and fully esterified forms, the composition of Kahre et al. is interpreted as inherently comprising partial esters of the recited acids, absent any indication by Kahre et al. to the contrary."

Applicants respectfully submit that the Examiner's statement is based on pure speculation and not on the teachings of Kahre et al. Applicants have thoroughly perused Kahre et al. and can find no teaching or suggestion that the esters utilized are partial esters or salts of partial esters. The only ester exemplified is a full ester.

The Examiner's presumption that production of an ester oil would inherently yield a mixture of partial and fully esterified forms is probably correct. However, the esters could be treated to remove partial esters or the partial esters could be present in such small amounts that they are considered impurities which would not make the present invention obvious. In fact, the production of the full esters would not provide a composition which would meet the 60:40 to 40:60 ratio of the alkyl polyglycoside to the partial ester. Applicants respectfully request that the Examiner reconsider the teachings of Kahre et al.

As pointed out above, Burns is not pertinent since the hydroxy polycarboxylic acid partial esters formed are not esters with a material which in the art is considered a fatty alcohol.

In regard to unexpected results, Applicants respectfully request that the Examiner reconsider the breadth of the claims and the nature of the comparative examples set forth. The alkyl glycosides tested contained either 12-14 or 8-18 carbon atoms in the alkyl group. The partial esters tested were a tartaric acid monolauryl ester sodium salt, a malic acid monolauryl ester sodium salt and a citric acid dicoco ester sodium salt. The cocyl ester was either esters of fatty alcohols containing 8-18 carbon atoms or at least 12-14 carbon atoms. Applicants respectfully submit that this range clearly covers a broad range of compounds which fall within the claimed compounds.

In addition, the useful partial esters claimed cover a relatively narrow group of compound and is sufficient to support the unexpected results.

Applicants respectfully submit that it is well established in patent law that one does not have to provide an example of every possible compound which falls within a claim but that a reasonable number of tests using a representative number of compounds all of which show the unexpected results is sufficient to provide a basis for unexpected results.

It appears that the Examiner is requiring that Applicants do a PhD thesis research project to convince the Examiner of the unexpected results. However, Applicants respectfully submit that in view of the narrow and small scope of the useful compounds claimed, and a showing that all of the compositions tested show the unexpected properties, Applicants respectfully submit that the showing is sufficient to show unexpected results.

At page 12 of the Official Action, the Examiner is questioning the data in Table 1 in regard to the unexpected foam stability shown by incorporating the composition of the present invention in an aqueous system. The Examiner appears to be comparing the data of the foam height to the data shown in Burns'. However, Applicants respectfully submit that the foam height is not what is in question, but the stability of the foam height. This is clearly shown in Table 1 wherein the foam stability of the compositions containing the $C_{12/14}$ cocoalkyl oligoglucoside tartrate alone or mixed with the tartaric acid monolauryl ester sodium salt show relatively poor foam stability. In addition, the $C_{12/14}$ cocoalkyl oligoglucoside tartrate alone shows a high irritation score which is ameliorated to a certain degree by including the tartaric acid monolaurylester sodium salt in the composition. Since Applicants respectfully submit that comparative examples C1-C4 clearly show the lack of foam stability and in addition a high irritation score. Applicants respectfully submit that the results for the foam stability and irritation score clearly show the unexpected properties of the compositions of the present

invention when compared to the composition of Burns and Burns in combination with a partial fatty alcohol ester of tartaric acid. Applicants respectfully request that the Examiner reconsider the showing of unexpected properties.

At page 13 in questioning the results of Table 1, the Examiner is setting forth a position which is taken in regard to interpretation of the teachings of Kahre et al.

The Examiner states Table 1 in the present application shows that the tartaric acid monolauryl ester of (I) (example 1, partial ester) has the same foam height but less irritation than the citric acid dicocoylester of (II)(example 3, full ester), when used with the same cocoalkyl oligoglucoside. The Examiner states "However, this comparison of (I) with (II) does not constitute a controlled test of the foaming capability and total irritation of partial esters versus full esters. Not only is the extent of esterification (partial or full) changed between (I) and (II), but the acids and alcohols tested in each example are also different (tartaric and lauryl in (I), and citric and cocoyl in (II). While it is possible that the conversion from full to partial ester has resulted in the lower irritation scored in example 1, it is also possible that substituting tartaric acid for citric acid, or lauryl alcohol for dicocoyl alcohol, resulted in the lower irritation score."

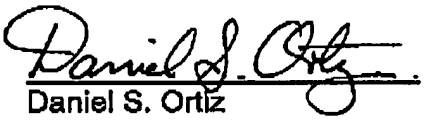
Applicants respectfully submit that the Examiner is faulting Applicants for providing too many different examples to show unexpected properties. Applicants submit that firstly, Applicants do not show any properties for full esters of hydroxy polycarboxylic acids mixed with polyglucosides. All of the esters shown in Table 1 are partial esters and fall within the claims. The examples 1, 2, 3, and 4 of compositions of the present invention when compared with Burns' compositions clearly show an increase in foam stability (not foam height) and a decrease in the total irritation score for all of the examples tested. Applicants respectfully submit that this is a clear showing of unexpected properties and covers a sufficient number of compounds to be relevant to the narrow composition as claimed.

Appl. No.: 10/088,732
Response dated September 6, 2005
Reply to Office action of May 4, 2005

At the last paragraph beginning on page 13, the Examiner appears to be indicating that the foaming capability of the citric acid dicocoylester/oligoglucoside mixture of example 3 appears to be well within the ranges of those given by the partial esters/oligoglucoside mixtures of examples 1, 2 and 4. Applicants submit that the basic foam height is not in question. The composition is not directed to increasing the foam height but increasing the foam stability. As shown in the Examples 1, 2, 3 and 4, a foam height and foam stability of the various composition varies but is in all cases substantially better than those shown by the materials tested in the comparative examples C1-C4. Applicants submit that the Examiner is questioning the foam height when the unexpected property is the stability of the foam and not the absolute value of the initial foam height.

In view of the amendment entered in the claims and the above discussion, Applicants respectfully submit that the application is in condition for allowance and favorable consideration is requested.

Respectfully submitted,



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Enc.: Hawley's Condensed Chemical Dictionary, page 570

Hawley's

Condensed Chemical

Dictionary

TWELFTH EDITION

Revised by

Richard J. Lewis, Sr.

VNR VAN NOSTRAND REINHOLD COMPANY
New York

$(HSCH_2CH_2COOCH_2)_2$.
Properties: Liquid, d 1.219 (25C), bp 175–195C, refr index 1.5150 (25C). Insoluble in water and hexane; soluble in alcohol, acetone, and benzene. Combustible.
Use: Cross-linking agent for polymers, especially epoxy resins, chemical intermediate.

glycol dimethyl ether. See ethylene glycol dimethyl ether.

glycol dipropionate. See ethylene glycol dipropionate.

glycolic acid. See hydroxyacetic acid.

glycol monoacetate. See ethylene glycol monoacetate.

glycolonitrile. (glyconitrile; formaldehyde cyanohydrin). $HOCH_2CN$.
Properties: Mobile, colorless, odorless oil. Supplied commercially as a 70% aqueous solution stabilized with phosphoric acid, bp 183C (slight decomposition), mp does not solidify when cooled to −72C, d 1.1039 (19C), refr index 1.4090 (25C), electrolytic dissociation constant $K = 0.843 \times 10^{-5}$ (25C).
Derivation: Formaldehyde and hydrogen cyanide.
Hazard: Toxic by ingestion, inhalation, and skin absorption.
Use: Solvent and organic intermediate.

glycol propionate. See ethylene glycol dipropionate.

glycol stearate. See ethylene glycol monostearate.

glycolysis. Enzymatic (anaerobic) decomposition of sugars, starches, and other carbohydrates with release of energy, a type of reaction occurring in yeast fermentation and in certain metabolic processes. Lactic acid is one of the products formed.

glyconic acid. See gluconic acid.

glyconitrile. See glycolonitrile.

glycoprotein. A composite molecule made up of a carbohydrate group and a simple protein. An example is the taste-modifying sweetener occurring in so-called "miracle fruit."

glycoside. One of a group of organic compounds, of abundant occurrence in plants which can be resolved by hydrolysis into sugars and other organic substances known as aglycones. Specifically glycosides are acetals which are derived from a combination of various hydroxy compounds with various sugars. They are designated individually as glucosides, mannosides, galactosides, etc. Glycosides were formerly called glucosides, but the latter term now refers to any glycoside having glucose as its sugar constitutent.

glycothiourea. See 2-thiohydantoin.

glycoylurea. See hydantoin.

glycyl alcohol. See glycerol.

glycyrrhizin. A glycoside of the triterpene group, the active principle of licorice root, from which it is extracted. It has an intensely sweet taste, and is used as a humectant in tobacco and a flavoring in confectionery and pharmaceutical products. The ammoniated derivative, which is 50 times as sweet as sucrose, is used as a foaming agent in root beer and mouthwashes; as a sweetener in chocolate, cocoa, and chewing gum; and as a taste-masking agent in pharmaceuticals such as aspirin. Its ability to exert strong synergistic action with sucrose makes it useful in low-calorie foods (from 30–100 ppm are effective).
See also sweetener, nonnutritive.

glyme. Trivial name for a series of glycol ethers used as aprotic solvents. The group includes monoglyme (bp 85C), ethyl glyme (bp 121C), diglyme (bp 162C), ethyl diglyme (bp 190C), triglyme (bp 216C), butyl diglyme (bp 256C), and tetraglyme (bp 276C). Each is separately listed and referred to its conventional name.

glyodin. (generic name for 2-heptadecyl-2-imidazoline acetate; 2-heptadecylglyoxalidine acetate). CAS: 556-22-9.
$C_{17}H_{35}C_3H_5N_2{\cdot}CH_3COOH$.
Properties: Light orange crystals, mp 62C, d 1.03, insoluble in water.
Derivation: Ethylenediamine and stearic acid.
Use: Fungicide (fruits and vegetables).

glyoxal. CAS: 107-22-2. OHCCHO.
Properties: Yellow crystals or light yellow liquid, mild odor, mp 15C, bp 51C, d 1.14 (20/20C), bulk d 10.0 lb/gal (20C), vapor has a green color and burns with a violet flame, refr index 1.3826 (20C), polymerizes on standing or in presence of a trace of water. An aqueous solution contains monomolecular glyoxal and reacts weakly to acid. Undergoes many addition and condensation reactions with amines, amides, aldehydes and hydroxyl-containing materials. Glyoxal VP resists discoloration.
Derivation: Oxidation of acetaldehyde.
Grade: 40% solution; pure, solid; VP.
Hazard: Mixture of vapor and air may explode.

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groups (poly
materials); b
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glyoxaline. Se

glyoxyldiureide

glyphosate. (
CAS: 1071-8
Use: Herbicid

glyphosine. C
sugar cane.

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GMP. Abbre
phate.
See guanosine
guanylate.

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